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(54) SELF-EXPANDING ENDOVASCULAR STENT

SELBSTEXPANDIERENDER, ENDOVASKULÄRER DILATATOR

DILATATEUR AUTO EXPANSIBLE

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Description

Technical Field

This invention relates to improvements of endovascular stent

Background Art

It is desirable in various situations that means be provided for expanding a constricted vessel portion or for maintaining an open passageway through a vessel portion.

For example, these situations can be those by esophageal strictures that are caused by esophageal carcinoma or esphageal metastasis, or those by strictures that resulted from the cancer of biliary system, urinary duct system and bronchial system.

The balloon expansion has been well known method of enlarging and maintaining the passageway of esophagus in these cases, but this method should be operated repeatedly for its temporary effects, and also it has no effects on the patients of serious strictures.

As alternatives, various artificial-esophagi have been used in the cases of esophageal strictures, but since they have no constriction and relaxation, the rate of esophageal rupture is high (30 - 40%) in the process of inserting them into the strictural area that has been caused by the cancer, and the high mortality rate due to mediastinitis results from rupture of esophagus. In addition, the patient has a great difficulty in swallowing due to narrow inner diameter (10 - 12 mm) of artificial esophagus, and obstruction of artificial esophagus occurred frequently due to food intake.

As the means of overcoming the difficulty, a device to hold the passageway enlarged using a stent was presented by U.S. patent No. 4,214,587. However, th device of the invention has the temporary effect in enlarging the passageway, there is still the problem that the endovascular lumen gets narrows after a long time.

To improve this disadvantages, U.S. patent No. 4,580,568 was offered. The stent of said invention includes a wire formed into a closed zig-zag configuration including an endless series of straight sections joined by bends. The stent is resiliently compressible into a smaller first shape wherein the straight sections are arranged side-by-side and closely adjacent one another for insertion into a larger second shape wherein said straight sections press against the walls of the passageway to maintain it open.

However, in a case that the stent of the 4,580,568 invention is put into use for a long time, it still has the problem that the lumen is narrowed, because the proliferated cells cover the stent thickly. There is no effect in the case of the stricture by cancer, because the cancer cells can pass through the straight sections.

Disclosure of Invention

In view of the foregoing, it is the main object of this invention to provide a self-expanding endovascular stent, which expands a constricted vessel portion and maintains an open passageway through a vessel portion for a long time without moving in a lumen.

It is another object of the present invention to provide a self-expanding endovascular stent, which prevents the cancer cells to penetrate into a stent.

To accomplish said purposes, this invention provides, a stent, which comprises a cylindrical frame formed by a plurality of unit structures; each of said unit structures being formed into a closed zig-zag configuration including an endless series of straight sections, joined by bends, and adjacent one another along the axis of the stent; connecting members, which connects said unit structures one another and a mesh, which is wrapped around the outside of said frame.

Another stent according to the present invention comprises a cylindrical frame formed by a plurality of unit structures; said unit structures formed into a closed zig-zag configuration including an endless series of straight sections, joined by bends, and arranged face to face into a shape of multistage; connecting members, which connects said unit structures one another; anti-migration members, which have the same structure with said unit structure, and placed in the ends of the upper and lower portions of said frame; and a mesh, which is wrapped around the outside of said frame.

Brief Description of Drawings

Fig. 1 is a development figure that illustrates a unit structure of a frame according to the present invention.

Fig. 2 is a perspective view of a first embodiment that illustrates a frame according to the present invention.

Fig. 3 is a development figure of said frame of the first embodiment of the invention.

Fig. 4 is a perspective view of the first embodiment according to the invention.

Fig. 5 is a view of showing a state that a stent of the first embodiment according to the present invention is placed and enlarged in a lumen.

Fig. 6 is a perspective view of a second embodiment according to the present invention that illustrates a frame.

Fig. 7 is a view of showing a state that a stent of the second embodiment of the present invention is placed and enlarged in a lumen.

Best Mode for Carrying out the Invention

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the

scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such applications of the principles of the invention as illustrated therein being contemplated as would normally occur of one skilled, in the art to which the invention relates.

Fig. 1 is a development figure that illustrates the unit structure of a frame according to the present invention; Fig. 2 is a perspective view of the first embodiment that illustrates a frame according to the present invention; Fig. 3 is a development figure of said frame of Fig. 2.

A frame 10 of the first embodiment comprises a reasonable number of unit structures 11 as shown in Fig. 1. The unit structure 11 is constructed of a wire, and the wire is preferably made of stainless steel. The unit structure 11 is formed into a closed zig-zag configuration, thereby forming a series of straight sections 111 and bends 112 as shown in Fig. 1. Both ends of the wire are joined to each other by welding, thereby forming an endless series of straight sections joined by bends.

Frame 10 is constructed in a way that a plurality of said unit structures 11 closely similar to each other and bends corresponding to each of the unit structures are adjacent one another along the axis of the stent. At this time, every unit structure is connected in tandem by a reasonable number of connecting members 31, 33, 35, 37, ---. These connecting members are joined appropriately between the bends of appointed unit structure such that they prevent each unit structure from being separated. The most preferable joint position of the connecting members is to be placed diagonally, regarding the connecting member 31 as a fiducial point as shown in Fig. 3. Namely, it is preferable to have a construction 31, 33, 35, and 37 as can be seen in Fig. 3. Also, the connecting members are not connected with every other bend and the frame 10 wherein an appropriate number of connecting members in one unit structure 11 i. e. ten connecting members in the first embodiment of Fig. 3 are connected to each other, has a plurality of diamond-like spaces 100. The number of the unit structure or the connecting members do not have a special meaning, and may be varied according to a state of a patient and/or convenience of production.

The space areas receive the straight section 111 when the straight section 111 is shrinked, making an elasticity variation with the bend 112.

A completed frame 10 has anti-migration members 41, 43 for preventing migration of a stent in a lumen that are equipped with barbs that jut outside. The anti-migration members 41, 43 are properly arranged and connected with the bends which the connecting members 31, 33, 35, 37 are not connected. Therefore, the stent 1 of the present invention does not move in a lumen.

All the unit structures, the connecting members, and the anti-migration members are made of the sane material like stainless steel, preferably are gilt.

The frame 10 is wrapped in a mesh 91, and upper and lower hem of the mesh 91 are folded towards inside, and both hems become respectively adhesive whereby a wire of the unit structure 11 is not exposed. It is preferable that the mesh is made of nylon and the nylon mesh is coated with silicon rubber.

The method of 587 U.S. patent or a method using a catheter in which the stent of the invention being compressed may be used in order to place the stent of the present invention at a position, namely a diseased part in a lumen.

The stent is fixed on inner walls of the lumen with the barb 411 of the anti-migration member, and though the stent is used for a long time, it does not migrate, and in addition thereto, pain that a patient may feel can be relieved, compared with conventional stent, because an outer wall of the stent 1 is wrapped with mesh 91. Furthermore, the silicon rubber coating on the mesh 91 can prevent that cancer cell and the like penetrate into the inside of the stent.

As a result of experimenting the first embodiment of this invention on patients with gastric cancer or esophageal cancer, following effects are obtained.

A. A patient with gastric cancer and esophageal spreading of gastric cancer came to Hospital of Cheon Buk Medical College on July, 1989. The symptoms of the patient were improved after six times medicine of anti-cancer. But the patent revisited to the medical college for an appearance of a dysphagia.

On January 8, 1990, an obstructed area of distal portion of esophagus due to spreading of gastric cancer, was enlarged with an esophageal balloon of 20 mm in diameter and 8 cm in length, and then a stent of 20 mm in external diameter and 8 cm in length was incubated into a strictural area of esophagus through a sheath of 10 mm.

After operation, the patient was able to eat liquid food and solid food, and in esophagogram performed in seven days after operation, a barium passed well through esophagus without any undercurrent or obstruction, and specific complications such as the migration of the stent or the rupture of the esophagus, did not occur.

After that, the patient left the hospital, and died of a generalized metastasis of gastric cancer on April, 1990. However, there was no problem with the function of the stent until just before the patient's death.

B. A patient with gastric cancer and esophageal metastasis came to Hospital of Cheon Buk Medical College owing to dysphagia on March 13, 1990.

After an obstructed portion of esophagus was enlarged with an esphageal balloon of 20 mm in diameter and 8 cm in length, a stent of 20 mm in external diameter and 10 cm in length was intubated into the distal portion of esophagus through the sheath of 10 mm in external diameter.

As a result of the operation, the patient was not able to eat even water, but after the stent was intubated into his lumen, the patient was able to taking

the liquid food and solid food, and a balium passed well through without any undercurrent or obstruction in esophagogram performed in seven days after the operation. When endoscope is performed on March 27, 1990, the endoscope of 10 mm in external diameter was passed through without any difficulty.

And in following up examination of esophagogram performed on August 10, 1990, any specific complications like the moving or the obstruction of the stent did not occur, and in addition, the patient was able to eat the liquid food and solid food.

C. A patient with the esophageal carcinoma was hospitalized in the Hospital of Cheon Buk Medical College, and took radiotherapy and medicated anticancer medicine five times, and then symptoms were improved, but the patient revisited to the hospital due to the dysphagia.

After the obstructed area of the esophagus was dilated with the esophageal balloon of 20 mm in diameter and 8 cm in length, the stent of 20 mm in external diameter and 12 cm in length was intubated into the obstructed area of the esophagus through the 10 mm sheath.

As a result of the treatment, the patient was able to eat liquid food and solid food, balium passed well through without any undercurrent or obstruction in esophagogram, and any complication like the migration of the stent or the rupture of the esophagus did not occur.

As medical appliance of the present invention is proved by the experiment on the above, since the expansile force of the stent that is intubated into an appointed area and is kept, is excellent, the outstanding effects that keep the stricture of passageway enlarged can be obtained.

The construction of the first embodiment as mentioned above is expected of preventing the migration of the stent, but since the distal ends of the anti-migration members 41, 43 have barbs that jut out externally, the possibility cannot be excluded that the barbs cause a patient to feel pain and lumen perforation, and when the stent is artificially transferred to set the position of the stent to rights, the lumen wall can be hurt.

Fig. 6 is a perspective view of a second embodiment of the present invention, and shows that a plurality of unit structures 21, 22, 23, 24 are linker, being expanding. The unit structures 21, 22, 23, 24 are identical with the unit structures of the first embodiment.

According to the second embodiment of this invention, the stent comprises the frame 20 formed by a plurality of connected unit structures 21, 22, 23, 24, and anti-migration members 42 and 44 placed in lower and upper portions of the frame 20. The frame 20 without anti-migration members 42 and 44 is almost same with the frame of the first embodiment of this invention except for the numbers of the unit structures and the length of connecting members 36, 38. The numbers of unit structures have no meaning in this invention. And the length of connecting members 36, 38 in the ends of the upper and lower portions of the frame 20 is a half of the length of the connecting members 31, 39 of the first embodiment of this invention.

The both side sections of the unit structures 21, 24 are connected with the anti-migration members 42 and 44 through the second connecting members 32, 34.

Anti-migration members 42 and 44 placed in the ends of the upper and lower portions of the frame 20 have the same structure as the unit structures 21, 22, 23, 24. But the anti-migration members 42 and 44 ate formed to be larger than the frame 20 in diameter. To connect the frame 20, and the anti-migration members 42 and 44, that are different from each other in diameter, is available through the second connecting members 32, 34. The second connecting member 34 connects a bend 381 or the end 381 of the connecting member 38 with a bend 442 of the anti-migration member 44. This connection is performed by welding.

Since the diameter of the anti-migration members 42 and 44 depends on the length of horizontal parts 321, 341 of the second connecting members 32, 34, it is important to determine the length thereof. Expansile parts 322, 342, expanded from the horizontal parts 321, 341 and bended vertically.

It is omitted in Fig. 6 that a mesh is wrapped around the outside of the frame 20.

The stent 2 formed as mentioned above keeps expanded unless farce is given thereto. In order to place the stent within an esophagus, a given introducing assembly such as an introducing tube, an esophageal balloon and a pusher catheter are pushed into a stricture in a compressed state.

As the introducing tube is removed over the pusher catheter, the compressed stent is automatically passed through and expanded.

Fig. 7 is an explanatory view of the state that the stent 2 placed within a lumen is radially expanded to stick to the lumen.

A stent that can be used for patients with esophageal carcinoma is described above, and if a stent was formed to be cylindrical between 8 mm to 10 mm in diameter, other applications of the stent are in the biliary, bronchial and urinary systems.

Claims

1. A stent comprising:

a cylindrical frame 10 formed by a plurality of unit structures 11, 12, 13, 14, 15, 16;

each of said unit structures 11, 12, 13, 14, 15, 16 being formed into a closed zig-zag configuration including an endless series of straight sections 111, joined by bends 112, and adjacent one another along the axis of the stent;

connecting members 31, 33, 35, 37, which connects said unit structures 11, 12, 13, 14, 15, 16;

and a mesh 91, which is wrapped around the outside of said frame 10.

2. A stent as claimed in claim in 1 wherein anti-migration members 41, 43 with barbs are installed in a central area 100 of said frame 10.

3. A stent as claimed in claims 1 and 2 wherein said frame 10, connecting members 31, 33, 35, 37, and anti-migration members 41, 43 are gilt.

4. A stent as claimed in claims 1 and 2, wherein said mesh 91 is coated with silicon rubber.

5. A stent comprising:
a cylindrical frame 20 formed by a plurality of unit structures 21, 22, 23, 24;
each of said unit structures 21, 22, 23, 24 being formed into a closed zig-zag configuration including an endless series of straight sections 211, joined by bends 212, and adjacent one another along the axis of the stent;
connecting members, which connect said unit 22, 23, 24;
anti-migration members 42 and 44, which have the same structure as said unit structure, and placed in the ends of the upper and lower portions of said frame; and
a mesh 91 which is wrapped around the outside of said frame 20.

6. A stent as claimed in claim in 5, wherein said anti-migration members 42 and 44 have larger diameters than the diameter of said frame 20, and are connected to said frame 20 by the second connecting members 32, 34.

7. A stent as claimed in claim 6, wherein the second connecting members 32, 34 consist of vertical parts 321, 341 and expansile parts 322, 342.

8. A stent as claimed in claims 5, 6 and 7, wherein the mesh is wrapped whole around the outside of said frame 20 and the anti-migration members 42 and 44.

9. A stent as claimed in claims 5 and 6, wherein said frame 20 and anti-migration members 42, 44 are gilt.

10. A stent as claimed in claims 5 and 6, wherein said mesh is coated with silicon rubber or urethane resin or the like.

Patentansprüche

1. Dilatator, bestehend aus:
einem zylindrischen Rahmen (10), der durch eine Vielzahl von Grundelementen (11, 12, 13, 14, 15, 16) gebildet wird, wobei jedes der Grundelemente (11, 12, 13, 14, 15, 16) in einer insich geschlossenen Zick-Zack-Form geformt ist, die eine endlose Folge von geraden Abschnitten (111) einschließt, die verbunden sind durch Biegungen (112), und die zueinander benachbart sind entlang der Dilatatorachse, sowie aus Verbindungselementen (31, 33, 35, 37), die diese Grundelemente (11, 12, 13, 14, 15, 16) verbinden,
und aus einem Gitter (91), das um die Außenfläche des Rahmens (10) gewunden ist.

2. Dilatator gemäß Anspruch 1,
wobei bewegungshindernde Teile (41, 43) mit Widerhaken in einer zentralen Fläche (100) des Rahmens (10) angeordnet sind.

3. Dilatator gemäß Anspruch 1 und 2,
wobei der Rahmen (10), die Verbindungselemente (31, 33, 35, 37) und die bewegungshindernden Teile (41, 43) vergoldet sind.

4. Dilatator gemäß den Ansprüchen 1 und 2,
wobei das Gitter (91) mit Silicon-Kautschuk ummantelt ist.

5. Dilatator bestehend aus
einem zylindrischen Rahmen (20), der durch eine Vielzahl von Grundelementen (21, 22, 23, 24) gebildet wird,
wobei jedes der Grundelemente (21, 22, 23, 24) in einer insich geschlossenen Zick-Zack-Form geformt ist, die ein endlose Folge von geraden Abschnitten (211) einschließt, die durch Biegungen (212) verbunden sind, und die zueinander benachbart sind entlang der Dilatatorachse,
Verbindungselementen, die die Grundelemente (22, 23, 24) miteinander verbinden, bewegungshindernden Teilen (42 und 44), die die gleiche Struktur aufweisen wie die Grundelemente und die angeordnet sind an den Enden der oberen und unteren Bereiche des Rahmens sowie
aus einem Gitter (91), das um die Außenfläche des Rahmens (20) gewunden ist.

6. Dilatator gemäß Anspruch 5,
wobei die bewegungshindernden Teile (42 und 44) größere Durchmesser aufweisen als der Durchmesser des Rahmens (20) und die mit dem Rahmen (20) verbunden sind über zweite Verbindungsteile (32, 34).

7. Dilatator gemäß Anspruch 6,
wobei die zweiten Verbindungsteile (32, 34) aus vertikalen Teilen (321, 341) bestehen und aus ausdehnbaren Teilen (322, 342).

8. Dilatator gemäß Ansprüchen 5, 6 und 7,
wobei das Gitter um die gesamte Außenfläche des Rahmens (20) und um die bewegungshindernden Teile (42 und 44) gewunden ist.

9. Dilatator gemäß den Ansprüchen 5 und 6, wobei der Rahmen (20) und die bewegungshindernden Teile (42, 44) vergoldet sind.

10. Dilatator gemäß Ansprüchen 5 und 6, wobei das Gitter mit Silicon-Kautschuk oder Urethan-Kunstoff oder ähnlichem ummantelt ist.

Revendications

1. Prothèse comprenant :
   - une armature cylindrique 10 formée par une pluralité de structures unitaires 11,12,13,14,15,16 ;
   - chacune desdites structures unitaires 11,12,13,14,15,16 étant formée par une configuration fermée en zigzag incluant une série en continu de sections droites 111, assemblées par des courbures 112, et adjacentes les unes par rapport aux autres le long de l'axe de la prothèse ;
   - des organes de liaison 31,33,35,37 qui relient lesdites structures unitaires 11,12,13,14,15,16 ;
   - et un treillis 91, qui est enroulé autour de l'extérieur de ladite armature 10.

2. Prothèse selon la revendication 1, dans laquelle des organes anti-migration 41,43 munis de picots sont agencés dans une zone centrale 100 de ladite armature 10.

3. Prothèse selon les revendications 1 et 2, dans laquelle ladite armature 10, lesdits organes de liaison 31,33,35,37 et lesdits organes anti-migration 41,43 sont dorés.

4. Prothèse selon les revendications 1 et 2, dans laquelle ledit treillis 91 est revêtu de caoutchouc de silicone.

5. Prothèse comprenant :
   - une armature cylindrique 20 fermée par une pluralité de structures unitaires 21,22,23,24 ;
   - chacune desdites structures unitaires 21,22,23,24 étant formée par une configuration fermée en zigzag incluant une série en continu de sections droites 211, assemblées par des courbures 212, et adjacentes les unes par rapport aux autres le long de l'axe de la prothèse ;
   - des organes de liaison qui relient lesdites unités 22,23,24 ;
   - des organes anti-migration 42 et 44, qui présentent la même structure que ladite structure unitaire, et placés aux extrémités des parties supérieure et inférieure de ladite armature ; et
   - un treillis 91, qui est enroulé autour de l'extérieur de ladite armature 10.

6. Prothèse selon la revendication 5, dans laquelle lesdits organes anti-migration 42 et 44 ont des diamètres plus grands que le diamètre de ladite armature 20, et sont reliés à ladite armature 20 par les seconds organes de liaison 32,34.

7. Prothèse selon la revendication 6, dans laquelle les seconds organes de liaison 32, 34 comprennent des parties verticales 321,341 et des parties expansibles 322,342.

8. Prothèse selon les revendications 5, 6 et 7, dans laquelle le treillis est enroulé tout autour de l'extérieur de ladite armature 20 et des organes anti-migration 42 et 44.

9. Prothèse selon les revendications 5 et 6, dans laquelle ladite armature 20 et lesdits organes anti-migration 42, 44 sont dorés.

10. Prothèse selon les revendications 5 et 6, dans laquelle ledit treillis est revêtu de caoutchouc de silicone, ou de résine d'uréthane ou analogue.

FIG.1

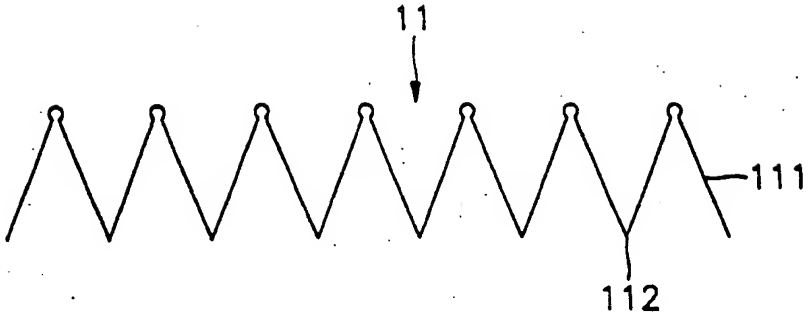

FIG.2

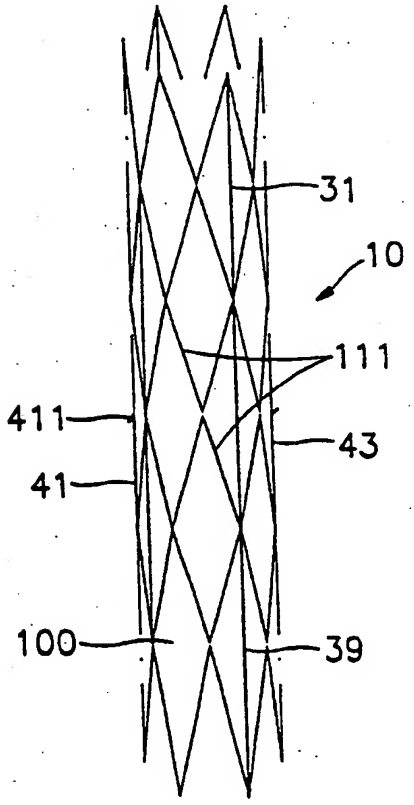

FIG.3

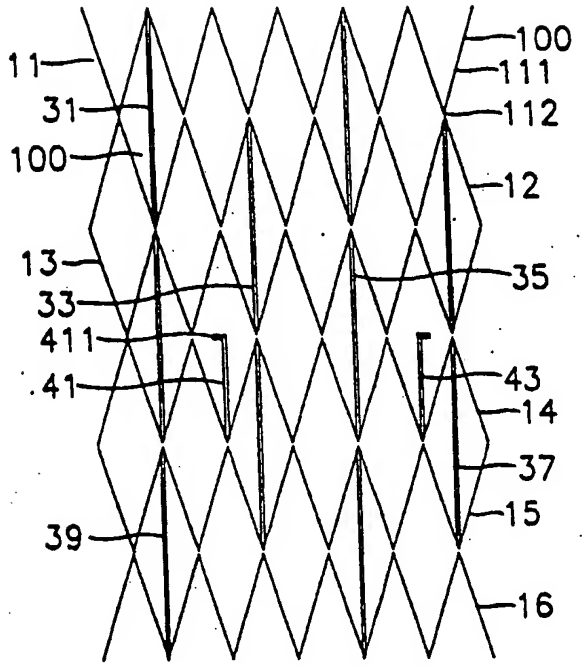

FIG.4

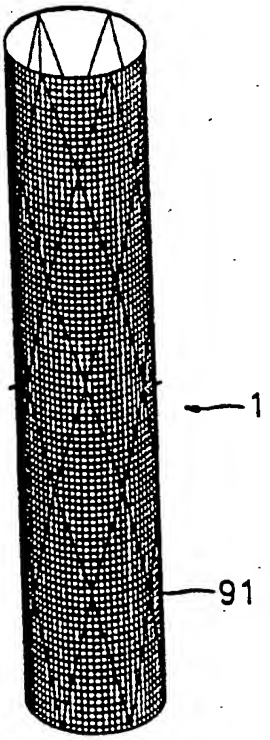

FIG.5

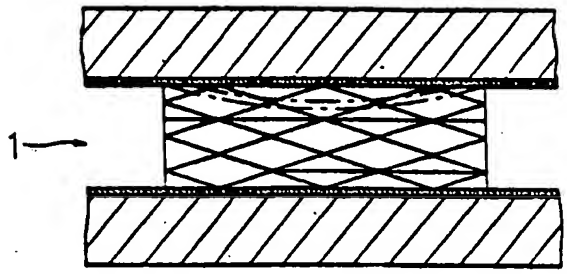

FIG.6

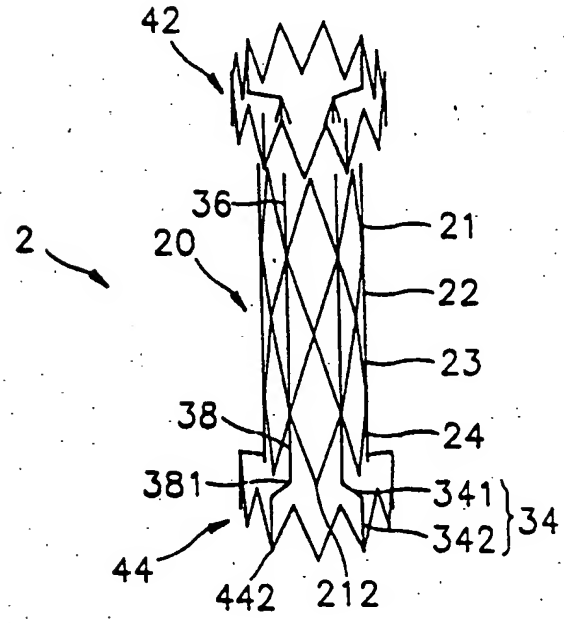

FIG.7